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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/506,956	03/24/2005	C. Mauli Agrawal	5660-00503	8795

35690 7590 01/23/2009

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EXAMINER	
NAFF, DAVID M	

ART UNIT	PAPER NUMBER
1657	

MAIL DATE	DELIVERY MODE
01/23/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/506,956	AGRAWAL ET AL.	
	Examiner	Art Unit	
	David M. Naff	1657	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *07 October 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,5-9,11-14,16-27,29-32 and 63* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1, 5-9, 11-14, 16-27, 29-32, and 63* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 10/7/08 has been entered.

An amendment of 10/7/08 amended claims 1, 18, 32 and 63, and canceled claims 2-4, 10, 15 and 128.

Claims examined on the merits are 1, 5-9, 11-14, 16-27, 29-32, and 63, which are all claims in the application.

Applicant is advised that should claim 13 be found allowable, claim 63 will be objected to under 37 CFR 1.75 as being a substantial duplicate thereof. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k).

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 24-31 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The specification fails to disclose cells producing the cellular products of claims 24-31 when the cells produce vascular endothelial growth factor (VEGF) as a cellular product in claim 1.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 11, 13-18 and 24-31 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 11 is confusing by repeating a portion of claim 1 that is not needed. It is suggested the portion of the claim be deleted from "subjecting" in line 1 to "wherein" in line 2, inclusive.

In claims 13, 14, and 16-18, "a" before "reactive gas" in line 2 should be changed to --- the --- to make clear the reactive gas is that in claim 1.

Claim 13 is unclear as to watts that would be used with the time range of 1 minute to 5 minutes to provide the energy range of claim 1.

Claims 24-31 are unclear how the cells can produce the cellular products of the claims when the cells produce VEGF as a cellular product as required by claim 1.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1, 5-9, 11-14, 16-19, 21, 23, 25, 27, 29, 30, 32 and 63 are rejected under 35 U.S.C. 103(a) as being unpatentable over Williams et al (4,927,676) in view of Mineau-Hanschke (6,582,391), and Mineau-Hanschke (6,419,920), and if necessary in further view of Lee et al (6,033,582), Hoffman et al (5,034,265 or 5,055,316).

The claims are drawn to method of preparing an implant by treating a bioresorbable polymeric substrate with a gas-plasma treatment by exposing the substrate to a reactive gas comprising oxygen at a supplied energy during gas-plasma treatment of between about 5 kJ and about 10 kJ, and exposing the treated substrate to living cells so a portion of the cells become coupled to the substrate, and wherein the coupled cells produce more of a product than cells coupled to an untreated substrate, and the cells produce vascular endothelial growth factor (VEGF) as least one cellular product.

Williams et al disclose attaching endothelial cells to a substrate by treating the substrate with a gas-plasma before attaching the cells (col 2, under "SUMMARY OF THE INVENTION", and col 4, lines 48-59). The gas used can be oxygen (col 4, line 51), and a preferred gas is a mixture of ammonia and oxygen (col 5, lines 31-32). The substrate with the attached cells is implanted.

Mineau-Hanschke ('391) discloses providing a medically useful polypeptide to a patient by providing a matrix containing cells that secrete the polypeptide and implanting the matrix (col 4, lines 17-31). The cells in the matrix can be implanted to produce a wide range of cellular products including various growth factors (col 18, lines 31-55).

Mineau-Hanschke ('920) discloses vascular endothelial growth factor as a cellular product (col 4, lines 41-42).

Lee et al disclose surface modification of medical implants by gas-plasma treatement using oxygen as the gas.

Hoffman et al ('265) disclose using gas-plasma treatment to improve compatibility of biomaterials.

Hoffman et al ('316) disclose gas-plasma treatment of a surface to provide tight binding of proteins to the surface.

It would have been obvious to attach cells to the substrate implanted of Williams et al that produce a cellular product when implanted as suggested by Mineau-Hanschke ('391) to obtain the benefit of cells producing the product *in vivo*. It would have been obvious to use cells that produce vascular endothelial growth factor as the product as suggested by Mineau-Hanschke ('920) to obtain the known function of vascular endothelial growth factor. It would have been within the skill of the art and obvious to select a preferred energy within the range of energy conditions disclosed by Williams et al (col 5, lines 17-23). Lee et al and Hoffman et al ('265 and '316) further disclose gas-plasma treatment of a substrate, and if needed would have suggested conditions that can be used. Cells attached to the plasma treated substrate will inherently produce more product than cells attached to an untreated substrate. The conditions of dependent claims would have been obvious from conditions disclosed by the references.

Claim Rejections - 35 USC § 103

Claim 20 is rejected under 35 U.S.C. 103(a) as being unpatentable over the references as applied to claims 1, 5-9, 11-14, 16-19, 21, 23, 25, 27, 29, 30, 32 and 63 above, and further in view of Berlowitz-Tarrant et al (5,840,387).

The claim requires human aortic endothelial cells.

Berlowitz-Tarrant et al disclose attaching aortic endothelial cells to a surface that can be an implant (col 5, lines 40-65).

When using cells that produce vascular endothelial growth factor as the cells of Williams et al as set forth above, it would have been obvious to use aortic endothelial cells as the cells as suggested by Berlowitz-Tarrant et al disclosing attaching aortic endothelial cells to a surface for implanting.

Claim Rejections - 35 USC § 103

Claim 22 is rejected under 35 U.S.C. 103(a) as being unpatentable over the references as applied to claims 1, 5-9, 11-14, 16-19, 21, 23, 25, 27, 29, 30, 32 and 63 above, and further in view of Smith et al (5,580,779).

The claim requires myocardial cells.

Smith et al disclose using myocardial cells to produce a peptide *in vivo* (col 5, lines 3-8).

When using cells that produce vascular endothelial growth factor as the cells of Williams et al as set forth above, it would have been obvious to use myocardial cells to produce a peptide as suggested by Smith et al.

Claim Rejections - 35 USC § 103

Claim 24 is rejected under 35 U.S.C. 103(a) as being unpatentable over the references as applied to claims 1, 5-9, 11-14, 16-19, 21, 23, 25, 27, 29, 30, 32 and 63 above, and further in view of Zonneveld et al (6,447,768).

The claim requires the cellular product to be a nucleic acid.

Zonneveld et al disclose delivering a nucleic acid *in vivo* with a cell that produces the nucleic acid to provide gene therapy (abstract and paragraph bridging cols 3 and 4.

When using cells that produce vascular endothelial growth factor as the cells of Williams et al as set forth above, it would have been obvious to use cells that produce a nucleic acid to provide gene therapy as suggested by Zonneveld et al.

Claim Rejections - 35 USC § 103

Claim 26 is rejected under 35 U.S.C. 103(a) as being unpatentable over the references as applied to claims 1, 5-9, 11-14, 16-19, 21, 23, 25, 27, 29, 30, 32 and 63 above, and further in view of Beckmann et al (6,306,615).

The claim requires the cellular product to be beta-tubulin.

Beckmann et al disclose beta-tubulin-producing cells (col 16, lines 15-19).

When using cells that produce vascular endothelial growth factor as the cells of Williams et al as set forth above, it would have been obvious to use cells that produce beta-tubulin to obtain its function as suggested by Beckmann et al.

Claim Rejections - 35 USC § 103

Claim 31 is rejected under 35 U.S.C. 103(a) as being unpatentable over the references as applied to claims 1, 5-9, 11-14, 16-19, 21, 23, 25, 27, 29, 30, 32 and 63 above, and further in view of Newman et al (6,087,331).

The claim requires platelet-endothelial cell adhesion molecule-1 as a cellular product.

Newman et al disclose therapeutic use of platelet-endothelial cell adhesion molecule-1 and cells transformed to produce platelet-endothelial cell adhesion molecule-1.

When using cells that produce vascular endothelial growth factor as the cells of Williams et al as set forth above, it would have been obvious to use cells that produce platelet-endothelial cell adhesion molecule-1 as suggested by Newman et al.

Response to Arguments

The amendment urges that while Williams et al disclose an energy range that encompasses the claimed narrower energy range, Williams et al do not disclose the result of the quantity of oxide radicals produced as shown by Tables 2-4 of the specification when using the claimed energy range of 5 kJ to 10 kJ. The amendment further urges that Williams et al do not disclose oxygen as a gas. However, Williams et al disclose the gas can be oxygen and, also disclose using a mixture of ammonia and oxygen. The claims do not exclude a mixture of oxygen and ammonia. Williams et al disclose plasma treatment conditions that provide an energy range that encompasses the claimed energy range, and selecting preferred optimum conditions within the range of conditions suggested by Williams et al to provide the claimed energy range would have required merely limited routine experimentation and been obvious. Additionally, procedures of the Tables that provided energy within the range of the claims used a DL-PLA substrate, only oxygen as the gas and a temperature less that 50^0C. It cannot be assumed the same result of oxide radical production will be obtained when using other substrates, oxygen in a mixture with other gases and a temperature above 50^0C.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David M. Naff whose telephone number is 571-272-0920. The examiner can normally be reached on Monday-Friday 9:30-6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jon Weber can be reached on 571-272-0925. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/David M. Naff/
Primary Examiner, Art Unit 1657

DMN
1/20/09